

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**CuraMedical B.V.  
Industrieweg 6B  
1566 JP Assendelft  
The Netherlands**

for the scope

**Sterile haemostatic absorbable gelatine sponge and powder  
sterile haemostatic absorbable oxidized and oxidized regenerated cellulose fabric  
sterile non-absorbable haemostatic bone wax  
sterile haemostatic absorbable gelatine sponge with  
surface modification for increased tissue adhesion  
(see attachment)**

has introduced and applies a

**Quality System**

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system  
meets all requirements according to

**Annex II – excluding Section 4  
of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2020-04-30
Valid until	2024-05-26
Registration no.	D1169400028
Report no.	P19-01708-164064
Stuttgart	2020-04-30

  
Head of Certification Body



**Attachment of the certificate**

**No. D1169400028**

Date 2020-04-30

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Product category	Product	Class
Sterile haemostatic absorbable gelatine sponge and powder	CuraSpon®	III
sterile haemostatic absorbable oxidized regenerated cellulose fabric	CuraCel®	III
sterile haemostatic absorbable oxidized cellulose fabric	CuraTamp®	III
sterile haemostatic absorbable gelatine sponge with surface modification for increased tissue adhesion	TenaTac®	III
sterile non-absorbable haemostatic bone wax	CuraWax®	IIb



  
Head of Certification Body